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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/508,238	Berghof et al
Examiner	**Art Unit**
Jehanne Souaya	1634

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Oct 22, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *7, 8, 10, 12-14, 16, 17, 19, 22-24, and 26-45* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *7, 8, 10, 12-14, 16, 17, 19, 22-24, and 26-45* is/are rejected.

7) ☒ Claim(s) *19, 31, and 32* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on 10/22/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/508,238 is acceptable and a CPA has been established. An action on the CPA follows.

2. Currently, claims 7, 8, 10, 12-14, 16, 17, 19, 22-24, and 26-45 are pending. Claim 45 is newly added. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. The action is NON-FINAL.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claims 19, 31, and 32 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. .

Claim 23 is dependent from claim 10 but does not further limit claim 10 as it contains exactly the same language as claim 10, that is the claims are identical in scope. Claims 31, 19, and 32 are drawn to a molecule which can be as short as 10 nucleotides (claim 31) or 15 nucleotides (claim 32, claim 19), however, these claims depends from claim 30 which necessarily stipulates that the molecule is at the very least, either 20 or 23 nucleotides long.

5. Applicant is advised that should claim 32 be found allowable, claim19 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 19 and 32 appear to be duplicate claims as they appear to be identical in scope, unless the recitation of "contains 15-30 nucleotides" (recitation of claim 32) is meant to encompass a sequence which comprises 15-30 nucleotides (that is, it can have nucleic acid sequences on either side of 30 nucleotides).

Claim Rejections - 35 USC § 112

Written Description

6. Claims 12-14, 16, 17, 19, 22, 26-29, and 31-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims containing the recitations: " a nucleic acid molecule comprising a nucleic acid sequence from the group consisting of SEQ ID NOS 3-5 and the complement of SEQ ID NOS 3-5, wherein the nucleic acid molecule is a shortened sequence as compared to that of SEQ ID NO 1", "a nucleic acid molecule comprising at least 10 contiguous nucleotides from a nucleic acid sequence from the group consisting of SEQ ID NO 3-5 and the complement of SEQ ID NO 3-5", "a nucleic acid molecule comprising at least 10 contiguous nucleotides wherein said molecule corresponds in 9 out of 10 [or 8 out of 10, claim 39; or is 90% homologous to in at least 10 contiguous nucleotides] contiguous nucleotides to a nucleic acid sequence selected from the group consisting of SEQ ID NO 4, 5, and the complements of SEQ ID NO 4 and 5, and claims that depend therefrom encompass sequences, kits containing sequences, and methods using sequences from the 23s-5s intergenic spacer regions of any Pseudomonas species or specifically different Pseudomonas aeruginosa strains that have not been taught or described in the specification. As explained in the 112/2nd paragraph rejection below, it is unclear if such recitation encompasses fragments of SEQ ID NO 1 that contain any one of SEQ ID NOS 3-5, or their complements, or whether the language "wherein the nucleic acid molecule is a shortened sequence as compared to that of SEQ ID NO 1" is intended as merely an upper length limitation such that the claims encompass any nucleic acid molecule that contains any one of SEQ ID NO 3-5 or their complements, but can have any number of nucleotide sequence on either side such that the resulting nucleic acid molecule, while not being longer than SEQ ID NO 1, contains other nucleotides than SEQ ID NO 1. If the latter is the case, such recitation lacks sufficient

written description as it is unclear from the specification if SEQ ID NO 1 is the full length sequence of the 23s-5s intergenic spacer region of Pseudomonas aeruginosa ATCC 10145. The specification, at page 15, lines 9-10, recites "the sequence of Pseudomonas aeruginosa (ATCC 10145) *in the region of the 23s/5s intergenic region* is SEQ ID NO 1". From this disclosure, however it is unclear whether SEQ ID NO 1 is the full length 23s-5s intergenic spacer region, therefore, the claims encompass intergenic spacer sequences that have not been taught or described in the specification. It is noted that methods of using nucleic acid molecules that lack sufficient written description also lack description.

Further, the recitation of 90% homologous in claim 42, or "10 contiguous nucleotides correspond to said nucleic acid in 9 out of 10 [or 8 out of 10] contiguous nucleotides" in claims 28, 29, 36, and 39, encompass sequences to the intergenic spacer region of any Pseudomonas species, including those that are unknown in the art, which have not been taught or described in specification. The specification only teaches the nucleic acid sequence of a *region* of the 23s-5s [SEQ ID NO 1] intergenic spacer from Pseudomonas aeruginosa, as well as the nucleic acid sequences *consisting* of the sequences of SEQ ID NOS 3-5. The claimed sequences, however, read on the full intergenic spacer region of 23s-5s from any species of Pseudomonas. With respect to claim 22, the claim reads on any sequence such that 20% of it's nucleotides can be modified in each string of 10 successive nucleotides. Such a claim would read on a sequence only having 60% complementarity to SEQ ID NO 3, 4, or 5.

The claimed invention represents a broad genus for which a representative number of species of such a genus must be disclosed to fulfill the description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date, applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of the isolated nucleic acids of SEQ ID NOS 1 and 3-5, or to methods of using such a broad genus of nucleotides, the specification fails to show that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Response to Arguments

The response traverses the rejection. The response cites *In re Edwards*,568 F.2d 1349 (C.C.P.A. 1970) as the lead case on the written description requirement. The response further asserts that determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan. These arguments have been thoroughly reviewed but were found unpersuasive as the claims still encompass the full intergenic spacer region of 23s-5s from any species of Pseudomonas. It is further noted, that the claims are sufficiently broad as to encompass unknown sequences. With regard to the citation of *In re Edwards* these arguments have been thoroughly reviewed but were found unpersuasive. Firstly, the written description guidelines applied by the examiner are based on the *Regents of the*

University of California v. Eli Lilly decision in 1997 which is directed to nucleic acids, whereas the CCPA decision in *In re Edwards* was in 1970. Secondly, the examiner has not required that the specification must outline each and every sequence encompassed by the claims, but a representative number of the species encompassed by the broadly claimed genus. The disclosed structural feature: an oligomer of SEQ ID NO 1 or oligomers within it, SEQ ID NOS 3-5, does not constitute a substantial portion of the claimed genus of sequences from any species, strain, or isolate of Pseudomonas, or the claimed genus of genes from any source. One of skill in the art, would not be able to envision the detailed chemical structure of the encompassed nucleic acid molecules, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it, the polynucleotide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it

obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

For these reasons and the reasons made of record above, and in previous office actions, the rejection is maintained.

Indefinite

7. Claims 7, 8, 10, 12-14, 16, 17, 19, 22-24, and 26-45 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 30, 33, 36, 39 and 42 are indefinite in the recitation of "an isolated nucleic acid molecule as a component of a kit" as it is unclear if the claims are directed to a single nucleic acid molecule or to a kit containing a single nucleic acid molecule.

B) Claims 26 - 31, 33, 34, 36, 37, 39, 40, 42, 43, and 45 are indefinite in the recitation "is a shortened sequence as compared to that of SEQ ID NO 1..." and "contains 10 to not more nucleotides than SEQ ID NO 1" as it is unclear if the claim is directed to a fragment of SEQ ID NO 1, that is the nucleic acid molecules only contain contiguous sequences of SEQ ID NO 1, or if the recitation of SEQ ID NO 1 is used merely as an upper length limitation wherein the nucleotides on either side of the recited sequences do not have to be contiguous sequences from SEQ ID NO 1". Furthermore, the latter recitation is indefinite as it is unclear from the word "contains" as to whether it is drawn to "open" language (ie: comprises) or "closed language" (ie: consists). In other words it is unclear if in reciting" contains 10 to not more nucleotides than

SEQ ID NO 1" the claim is setting forth an upper and lower length limitation for the complete isolated nucleic acid molecule.

C) Claims 19, 31, and 32 are indefinite because they do not further limit claim 30, but instead appear to be broader. Claim 30 is directed to a nucleic acid molecule comprising a sequence of SEQ ID NO 3, SEQ ID NO 4, or SEQ ID NO 5, which are a 20mer, and 23mers respectively, therefore it is unclear how a sequence that contains any of those sequences can only be 10 nucleotides long (claim 31), or 15 nucleotides long (claims 19 and 32).

D) Claim 36 is indefinite in the recitation of "comprising at least 10 contiguous nucleotides wherein said molecule corresponds in 9 out of 10 contiguous nucleotides to a nucleic acid sequence selected..." as it is unclear if the nucleic acid molecule is meant to comprise 9 or 10 contiguous nucleotides from the recited SEQ ID NOS. The use of the word "contiguous" twice renders the claim indefinite as it is unclear if the first recitation (10 contiguous) is meant to provide a lower length limitation to the claimed nucleic acid molecule.

E) Claim 36 is indefinite in the recitation of "comprises is" in the 5th line of the claim. It is unclear if the nucleic acid molecule comprises SEQ ID NO 1, is SEQ ID NO 1, comprises a shortened sequence of SEQ ID NO 1, or is a shortened sequence of SEQ ID NO 1.

F) Claim 39 is indefinite in the recitation of "said 10 contiguous nucleotides correspond to said nucleic acid molecule in 8 out of 10 contiguous nucleotides" as it is unclear if the lower length limitation of the claimed nucleic acid molecule is 8 or 10 nucleotides. It appears that claim is directed to a nucleic acid molecule that comprises 10 contiguous nucleotides from

SEQ ID NO 4 or SEQ ID NO 5, and wherein the nucleic acid molecule can be as short as 8 nucleotides long.

G) Claim 42 is indefinite as it is unclear if only 10 contiguous nucleotides of the nucleic acid molecule are 90% homologous to SEQ ID NO 4 or 5, or if the full length nucleic acid molecule is 90% homologous to SEQ ID NO 4 or 5. The claim is further indefinite in the recitation of "allow for the detection of bacteria of the Pseudomonas genus" as it is unclear if such is meant to be a structural limitation to the claimed nucleic acid sequences, and if so, how. It is unclear if the recitation is meant to be a property of the claimed sequences, but that the sequences don't necessarily detect Pseudomonas genus.

H) Claim 13 lacks sufficient antecedent basis for the recitation of "the group of bacteria" as neither claim 13, nor claim 12 recite a "group of bacteria".

I) Claim 17 lacks sufficient antecedent basis for the recitation of "the to-be-detected" bacteria as neither claim 17, nor claim 12 recite "to-be-detected" bacteria, nor do the claims stipulate which bacteria is meant "to be detected" and "not to be detected". For example, is "Pseudomonas aeruginosa" to be detected or "not to be detected"?

J) Claim 17 lacks sufficient antecedent basis for the recitation of '"the region"of a nucleic acid sequence according to claim 30"'. It is unclear which "region" is being stipulated as neither claim 17 or claim 30 make such clear. The metes and bounds of the claim are therefore unclear.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in-
>
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
>
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

9. Claims 31, and 33-44 are rejected under 35 USC 102(b) as being anticipated by Cuenoud et al (Nature, vol 375, pp 611-614; 1995, sequence provided).

Cuenoud et al teach a sequence that is 116 nucleotides long and contains at least 10 contiguous nucleotides of SEQ ID NO 3. The first 10 contiguous nucleotides of SEQ ID NO 3 are "contained" by the sequence of Cuenoud and are present at positions 4-13 of the sequence of Cuenoud. With regard to claims 35, 38, 41, and 44, the recitation of "contains 15-30" nucleotides is interpreted to encompass "open" terminology (ie: comprises) and therefore the limitation is not sufficient to distinguish the claimed nucleic acid molecule from that of Cuenoud. With regard to the recitation of "as a component of a kit" in the claims, the claims have been

interpreted to encompass single nucleic acid molecules. Furthermore, the use for the kit claims that the nucleic acid claims are dependent on carry no patentable weight as they merely recite intended uses for the products. With regard to claim 31, as the claim only stipulates a lower length limitation for nucleic acid molecules of claim 30, the claim is interpreted to encompass 10 contiguous nucleotides of the molecule of claim 30. [The fact that a reference anticipates a dependent claim and not the claim that it depends from is further evidence that the recitation of claim 31, as dependent on claim 30, is improper.]

10. Claims 31, 33, and 34 are rejected under 35 USC 102(e) as being anticipated by Thompson (US Patent 5,783,182; 102(e) date: 11/16/1995;).

Thompson teaches a sequence (10 nucleotides long, SEQ ID NO 50) that is the complement of SEQ ID NO 3 from positions 5-14 of SEQ ID NO 3. With regard to the recitation of "as a component of a kit" in the claims, the claims have been interpreted to encompass single nucleic acid molecules. Furthermore, the use for the kit claims that the nucleic acid claims are dependent on carry no patentable weight as they merely recite intended uses for the products. With regard to claim 31, as the claim only stipulates a lower length limitation for nucleic acid molecules of claim 30, the claim is interpreted to encompass 10 contiguous nucleotides of the molecule of claim 30. [The fact that a reference anticipates a dependent claim and not the claim that it depends from is further evidence that the recitation of claim 31, as dependent on claim 30, is improper.]

11. Claims 19 and 31-44 are rejected under 35 USC 102(a) as being anticipated by Mantynen et al (International Journal of Food Microbiology, vol. 36; 1997; pp 135-143; sequence provided).

Mantynen et al teach a sequence (25mer) that contains at least 10 contiguous sequences of SEQ ID NO 5 (positions 11-20 of SEQ ID NO 5 correspond to positions 13-22 of the sequence taught by Mantynen et al). With regard to the recitation of "as a component of a kit" in the claims, the claims have been interpreted to encompass single nucleic acid molecules. Furthermore, the use for the kit claims that the nucleic acid claims are dependent on carry no patentable weight as they merely recite intended uses for the products. With regard to claims 32 and 19, the claimed nucleic acid molecule has been interpreted to encompass the sequence taught by Mantynen as it is unclear how many nucleotides from the claimed SEQ ID NOS are present in the molecule of claims 19 and 32 (see 112/2nd paragraph rejection above). With regard to claim 31, as the claim only stipulates a lower length limitation for nucleic acid molecules of claim 30, the claim is interpreted to encompass 10 contiguous nucleotides of the molecule of claim 30. [The fact that a reference anticipates a dependent claim and not the claim that it depends from is further evidence that the recitation of claim 31, as dependent on claim 30, is improper.]

12. Claims 31, and 33-44 are rejected under 35 USC 102(b) as being anticipated by Smith et al (Journal of Biological Chemistry, vol. 265, pp 13335-13343; 1990, sequence provided).

Smith et al teach a sequence (41mer) that contains, at positions 12-21, the first 10 contiguous nucleotides of SEQ ID NO 5. With regard to claims 35, 38, 41, and 44, the recitation of "contains 15-30" nucleotides is interpreted to encompass "open" terminology (ie: comprises) and therefore the limitation is not sufficient to distinguish the claimed nucleic acid molecule from that of Smith et al. With regard to the recitation of "as a component of a kit" in the claims, the claims have been interpreted to encompass single nucleic acid molecules. Furthermore, the use for the kit claims that the nucleic acid claims are dependent on carry no patentable weight as they merely recite intended uses for the products. With regard to claim 31, as the claim only stipulates a lower length limitation for nucleic acid molecules of claim 30, the claim is interpreted to encompass 10 contiguous nucleotides of the molecule of claim 30. [The fact that a reference anticipates a dependent claim and not the claim that it depends from is further evidence that the recitation of claim 31, as dependent on claim 30, is improper.]

13. Claims 19 and 31-44 are rejected under 35 USC 102(b) as being anticipated by Rink et al (Chemical Research in Toxicology; vol. 9, no. 2, 1996; pp 382-389; sequence provided).

Rink et al teach a sequence (15mer) that contains at least 10 contiguous sequences of SEQ ID NO 4 (positions 1-10 of SEQ ID NO 4 correspond to positions 4-13 of the sequence taught by Rink et al). With regard to the recitation of "as a component of a kit" in the claims, the claims have been interpreted to encompass single nucleic acid molecules. Furthermore, the use for the kit claims that the nucleic acid claims are dependent on carry no patentable weight as

they merely recite intended uses for the products. With regard to claims 32 and 19, the claimed nucleic acid molecule has been interpreted to encompass the sequence taught by Rink et al as it is unclear how many nucleotides from the claimed SEQ ID NOS are present in the molecule of claims 19 and 32 (see 112/2nd paragraph rejection above). With regard to claim 31, as the claim only stipulates a lower length limitation for nucleic acid molecules of claim 30, the claim is interpreted to encompass 10 contiguous nucleotides of the molecule of claim 30. [The fact that a reference anticipates a dependent claim and not the claim that it depends from is further evidence that the recitation of claim 31, as dependent on claim 30, is improper.]

14. Claims 19 and 31-44 are rejected under 35 USC 102(e) as being anticipated by Liskay et al (US Patent 6,191,268; 102(e) date is 12/9/1994; sequence provided).

Liskay et al teach a sequence (22mer, SEQ ID NO 143) that contains at least 10 contiguous sequences of SEQ ID NO 4 (positions 1-10 of SEQ ID NO 4 correspond to positions 2-11 of the sequence taught by Liskay et al). With regard to the recitation of "as a component of a kit" in the claims, the claims have been interpreted to encompass single nucleic acid molecules. Furthermore, the use for the kit claims that the nucleic acid claims are dependent on carry no patentable weight as they merely recite intended uses for the products. With regard to claims 32 and 19, the claimed nucleic acid molecule has been interpreted to encompass the sequence taught by Liskay et al as it is unclear how many nucleotides from the claimed SEQ ID NOS are present in the molecule of claims 19 and 32 (see 112/2nd paragraph rejection above). With

regard to claim 31, as the claim only stipulates a lower length limitation for nucleic acid molecules of claim 30, the claim is interpreted to encompass 10 contiguous nucleotides of the molecule of claim 30. [The fact that a reference anticipates a dependent claim and not the claim that it depends from is further evidence that the recitation of claim 31, as dependent on claim 30, is improper.]

Response to Arguments

With regard to the arguments in the response with regard to the recitation of "as a component of a kit", as stated in the rejections above, the use for a kit carries no patentable weight. With respect to the instantly claimed nucleic acid molecules, the rejections above were set forth to single nucleic acid molecules, and not to kits containing such, as the claims are drawn to single nucleic acid molecules and not to kits (see 112, 2nd para rejection above as well). Further, the use for the kits recited in claims 26-29 only specify an intended use for the claimed nucleic acid molecules and do not carry patentable weight. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been

established. In re Best, 195 USPQ 430,443 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

15. Claims 12-14, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kur et al. (Acta Microbiologica Polonica, vol. 44, pp 111-117; 1995).

Kur et al teach using 40 clinical strains of *Pseudomonas aeruginosa* and PCR using primers to amplify the 16s-23s spacer region to detect the bacteria in samples (see abstract and "Experimental" section, p. 112-113). It is noted that Kur does not teach the nucleic acids of claims 26, 27, 28, or 29, however, claim 12 does not stipulate what part of the kit of claims 26-29 should be used. Therefore, the claim encompasses using "substances for analytical detection purposes" as specified in claims 26, 27, 28, and 29, which is taught by Kur (see for example dNTPs mixture or Taq polymerase taught by Kur on page 112, "Experimental" section: "DNA amplification"). With respect to claim 17, the claim further does not stipulate which "region" of a nucleic acid according to claim 30 is used, and therefore encompasses a nucleic acid molecule with a single or two nucleotides from the molecule of claim 30, which is taught by Kur (see amplification primers, p. 113, "Results" section).

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 26-29, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over (in the alternative) Cuenoud et al, Liskay et al, Rink et al, Smith et al, Mantynen et al, or Thompson, each in view of Ahern (The Scientist, vol. 9, 1995, from the Internet: pp 1-5).

The teachings of Cuenoud et al, Liskay et al, Rink et al, Smith et al, Mantynen et al, and Thompson are outlined above. Although neither Cuenoud et al, Liskay et al, Rink et al, Smith et al, Mantynen et al, or Thompson teach the nucleic acids in kit format, Ahern the advantages of providing reagents in kit format. Ahern specifically teaches that "more researchers are buying premade reagents and kits because they are convenient and save time (see p. 4, 2nd para), and that putting products in kit format offer scientists the opportunity to better manage their time (see p. 4, first para). Therefore, (with regard to claims 26-29 and 45), it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to package the sequences of Cuenoud et al, Liskay et al, Rink et al, Smith et al, Mantynen et al, or Thompson, in kit format for the purposes of providing probes and primers in convenient format to make detecting the sequences of Cuenoud et al, Liskay et al, Rink et al, Smith et al, Mantynen et al, and Thompson, easier to perform and further to provide preweighed,

premeasured reagents to reduce sample handling and experimental error. Further, the use for the kits recited in claims 26-29 only specify an intended use for the claimed nucleic acid molecules and do not carry patentable weight. Intended used does not impart patentable weight to a product. See MPEP 2111.03:

> Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430,443 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Conclusion

17. No claims are allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
1/13/03